PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference MERL/20401577/SJ/JW/jt	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/SG2004/000319	International filing date *(day/month/year)* 30 September 2004	Priority date *(day/month/year)* 7 November 2003
International Patent Classification (IPC) or national classification and IPC **Int. Cl.** [7] A61M 29/00, A61F 2/06, A61B 17/12		
Applicant MERLIN MD PTE (et al.)		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
25 April 2005	11 August 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer MATTHEW FORWARD Telephone No. (02) 6283 2606

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SG2004/000319

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☒ the description:

pages **1-18** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

☒ the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* **19-22** received by this Authority on with the letter of 8 August 2005
pages* received by this Authority on with the letter of

☒ the drawings:

pages **1/4-4/4** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-27	YES
	Claims	NO
Inventive step (IS)	Claims 1-27	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-27	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 US 2003/0093111 A1

D2 WO 1998014137 A1

D3 EP 0947204 A2

D4 US 6024765 A

D5 EP 754435 A1

D6 EP 1391184 A1

The present amended claims define a stent for insertion into a bodily vessel for treatment of an aneurysm or ischemic diseases, wherein the stent is made from a platinum alloy selected from the group consisting of of platinum:iridium alloy, platinum;tungsten alloy, platinum:rhodium:ruthenium alloy, platinum:rhodium alloy and platinum;nickel alloy; and wherein the platinum;iridium alloy has a composition of about 70-80% of platinum and 20-30% iridium; wherein the platinum:tungsten alloy has a composition of about 85-95% of platinum and 5-15% of tungsten; wherein the platinum:rhodium:ruthenium alloy has a composition of about 70-85% of platinum, 1—20% of rhodium and 3-10% of ruthenium; wherein the platinum:rhodium alloy has a composition of about 60-80% of platinum and 20-40% of rhodium; and wherein the platinum:nickel alloy has a composition of about 80-90% of platinum and 10-20% of nickel.

NOVELTY AND INVENTIVE STEP: Claims 1-27

D1 discloses a vaso-occlusive device of metallic wire and methods of this device to treat patients by implanting such devices at the site of abnormal blood flow; the metallic wire can comprise a metal selected from the group consisting of platinum, tungsten, rhenium, rhodium, ruthenium, nickel and alloys thereof. Claims 1-27 are new and involve inventive step in view of this document.

D2 discloses a radially expandable stent which is formed of fine wire (10), the wire comprises an alloy selected from the group consisting of PT-Ir with 90 wt % Pt and 10 wt % Ir. Claims 1-27 are new and involve inventive step in view of this document.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: V;

D3 discloses an endoprosthesis. In preferred embodiment the body structure includes an elongated central cylindrical core and an elongated outer tubular member disposed around the core. One of the first and second materials comprises the core and the other comprises the tubular member. The first material is preferably selected from the group consisting of platinum, iridium, tungsten alloys thereof and any combination thereof. Claims 1-27 are new and involve inventive step in view of this document.

D4 discloses an implantable vaso-occlusive coil which is implanted using minimally invasive surgical techniques. The material used in constructing a vaso-occlusive member may be any of a wide variety of materials: alloys of metals of Platinum Group, especially platinum, rhodium. Claims 1-27 are new and involve inventive step in view of this document.

D5 discloses a vaso-occlusive device with helically wound coil made of Pt, Rh, W or their alloys. Claims 1-27 are new and involve inventive step in view of this document.

D6 discloses an expandable multi-layer tubular structure useful as a surgical stent which has two or more layers. The different layers can be made from Pt-Ir alloy. Claims 1-27 are new and involve inventive step in view of this document.

WE CLAIM:

1. A stent for insertion into a bodily vessel for treatment of an aneurysm or ischemic diseases,

wherein the stent is made from a platinum alloy selected from the group consisting of platinum:iridium alloy, platinum:tungsten alloy, platinum:rhodium:ruthenium alloy, platinum:rhodium alloy and platinum:nickel alloy; and

wherein the platinum:iridium alloy has a composition of about 70-80% of platinum and 20-30% iridium;

wherein the platinum:tungsten alloy has a composition of about 85-95% of platinum and 5-15% of tungsten;

wherein the platinum:rhodium:ruthenium alloy has a composition of about 70-85% of platinum, 10-20% of rhodium and 3-10% of ruthenium;

wherein the platinum:rhodium alloy has a composition of about 60-80% of platinum and 20-40% of rhodium; and

wherein the platinum:nickel alloy has a composition of about 80-90% of platinum and 10-20% of nickel.

2. The stent according to claim 1, wherein the stent comprises a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces therebetween, said generally tubular structure expandable from a first position to a second position, wherein said tubular structure expands radially outwardly to the second position such that the exterior surface of said structure engages with the inner surface of the bodily vessel so as to maintain a fluid pathway through said bodily vessel.

3. The stent according to claim 1, wherein the stent is a self-expandable stent.

4. The stent according to claim 1, wherein the platinum:tungsten alloy has a composition of about 90-95% of platinum and 5-10% of tungsten.

5. The stent according to claim 1, wherein the platinum:rhodium:ruthenium alloy has a composition of about 75-80% of platinum, 12-18% of rhodium and 5-10% of ruthenium.

6. The stent according to claim 1, wherein the platinum:rhodium alloy has a composition of about 65-75% of platinum and 25-35% of rhodium.

7. The stent according to claim 10, wherein the platinum:nickel alloy has a composition of about 85-90% of platinum and 10-15% of nickel.

8. The stent according to claim 1, wherein the stent is made from a wire of platinum:tungsten, platinum:iridium alloys, and welded to a predetermined tubular mesh.

9. The stent according to any one of claims 1 to 8, wherein the stent has a sidewall thickness of less than 0.0035".

10. The stent according to any one of claim 1 to 9, wherein the surface of the stent is modified by passive coatings.

11. The stent according to claim 10, wherein the coating is iridium oxide or titanium nitrate.

12. The stent according to claim 10, wherein the stent is coated with an external layer containing a pharmaceutically effective amount of therapeutic substances.

13. The stent according to claim 1, further comprising markers to enhance visibility and radiopacity of the device.

14. The stent according to claim 13, wherein the markers include end markers or center markers.

15. An implantable endovascular device for insertion into a bodily vessel to treat ischemic and hemorrhagic stroke, the device comprising:

a wire structure made from a platinum alloy selected from the group consisting of platinum:iridium alloy and platinum:tungsten alloy, the structure being expandable from a first position to a second position, and said structure expands radially outwardly to the second position such that an exterior surface of said structure engages with the inner surface of the bodily vessel so as to maintain a fluid pathway through said bodily vessel;

wherein the wire structure is formed by welding tubular shaped wire sections together and the exterior surface of the wire structure is defined by the welded wire sections;

wherein the device is longitudinally flexible, the flexibility being such that it is greater than a delivery catheter to deliver the device into the bodily vessel; ~~and~~

wherein the longitudinal flexibility of the device is defined by deflection of the device from a neutral line to 1mm when there is a force less then 8 grams;

wherein the platinum:iridium alloy has a composition of about 70-80% of platinum and 20-30% iridium; and

wherein the platinum:tungsten alloy has a composition of about 85-95% of platinum and 5-15% of tungsten.

16. The device according to claim 15, wherein the welding is laser welding.

17. A delivery system for inserting a ~~device an implantable medical device~~stent according to claim 1, within a bodily vessel, wherein the ~~device~~ stent is expandable by balloon inflation, the delivery system comprising a balloon delivery catheter and the ~~device~~stent, wherein the ~~expandable medical device~~stent is mounted onto the balloon of the delivery catheter.

18. A delivery system for inserting an implantable medical device according to claim 1, within a bodily vessel, wherein the ~~device~~ stent is self-expandable, the delivery system comprising a delivery catheter and the ~~device~~stent, wherein the ~~device~~ stent is mounted onto a distal portion of the delivery catheter.

19. The device according to claim 15, wherein the device is deployed at a pressure equal to or below 4atm.

20. The device according to claim 15, wherein the structure of the device provides a normalized radial force 18 to 19 grams per mm of length.

21. The device according to claim 20, wherein the structural support of the device provides 3 to 4% of deflection of the structure of the device together with natural pulsing of an intracranial vessel wall.

22. The device according to claim 15, wherein the device has a profile in a compressed delivery form of 0.020 inches.

23. The device according to claim 15, wherein the device has a profile between 0.014 to 0.016 inches and the profile of the device in an uncompressed delivery form is between 0.020 to 0.022 inches.

24. The device according to claim 15, wherein the device has uniform material distribution and wall coverage for providing support to a bodily vessel.

25. The device according to claim 15, wherein the ratio of the material is in the range of 12 to 16%, the range being dependent on the diameter of deployment.

26. The device according to claim 15, wherein the device comprises struts, the struts having a thickness and width less than or equal to 0.0028 inches.

27. The device according to claim 15, wherein the device has a surface to length ratio between 1.1 to 1.3mm²/mm to provide minimal vessel injury score.